DEPARTMENT OF HEALTH AND HUMAN SERVICES

Our Reference No. 95-0044

NOV 0 7 1996

Nancy L. Kercher
Alternate Responsible Head
Immunex Corporation
51 University Street
Seattle, WA 98101-2936

Dear Ms. Kercher:

Your request to supplement your product license application for Sargramostim to include new 500 mcg/ML and 1000 mcg/ML multidose liquid formulations containing 1.1% benzyl alcohol as preservative has been approved. The dating periods shall be 18 months for the 500 mcg/ML formulation and 3 months for the 1000 mcg/ML formulation when stored at 2-8°C.

We acknowledge your commitment of August 22, 1996 to place the first three lots of each of these formulations on stability testing for a period of at least 30 months, with testing at 6, 9, 12, 18, 24, and 30 months, and to withdraw from market any lots which fail one or more of the stability tests.

Please submit three copies of final printed labeling at the time of use and include part II of the label transmittal form with completed implementation information.

This information will be included in your product license application file.

Sincerely yours,

Giovanna Tosato, M.D.
Director
Division of Hematologic Products
Office of Therapeutics
Research and Review
Center for Biologics
Evaluation and Research